

DS cont.
genome, wherein said exogenous DNA sequence comprises the 5' 4.2 kb Sau3A - Kpn1 promoter fragment of the mouse whey acidic protein promoter, operably linked to a DNA encoding a polypeptide whereby said protein is expressed specifically in mammary cells of said transgenic mammal and said protein comprises a signal peptide, said peptide being effective in directing the secretion of said protein into the milk of said mammal[, and wherein said transgenic mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows].

DS
~~2016~~. (Amended) An isolated DNA molecule [capable of stimulating] which regulates the expression of a heterologous gene, wherein said DNA molecule consists of the 5' 4.2 kb Sau3A - Kpn1 promoter of the mouse whey acidic protein gene.

REMARKS

Claims 1-4, 6-9, 11, 12, 14 and 16 are pending in the application. Applicants have amended the claims to more clearly define what the applicants consider to be the invention. Support for the language "enzymatic activity of at least 50% as plasma-derived protein C" in amended claims 1, 6 and 11, 12 can be found at least in Table 5 of the specification. For the examiner's convenience, applicants attach a copy of the pending claims to this response as Exhibit 1. No new matter has been added by way of these amendments.

Applicants request the examiner to remove the finality of the pending office action under 37 CFR §1.129(a). A request and the required fee accompany this response.

Applicants thank the examiner and her supervisor for the courteous and helpful interview conducted at the USPTO on October 25, 1996, regarding the pending enablement rejection.

In the office action dated April 30, 1996, the examiner had rejected claims 1-4, 6-9, 11, 12 and 14 under 35 USC §112, first

paragraph. In the advisory action dated August 26, 1996, the examiner maintained the rejection, stating that:

[T]he arguments presented are not commensurate with the scope of applicants' claims. The production of protein C having no activity has not been taught as beneficial to the art. Likewise the mere production absent some recoverable quantity or measurement is not seen as having an enabled use. Applicants' evidence that cows have been produced which make a heterologous protein in their milk does not broadly enable any protein given the art's silence on transgenic cows as bioreactors.

Advisory action at page 1, paragraph 4. Accordingly, applicants understand the examiner's position to be that the specification does not support (1) the production of a form of protein C that is not biologically active, and (2) the production of transgenic cows. Applicants further understand that the first basis for rejection applies to claims 1, 6 and 11, while the second basis for rejection applies to claims 12 and 14. Applicants respectfully submit that the present amendments overcome these bases for rejection.

To expedite prosecution, applicants have amended claims 1, 6 and 11 to include a characterization of the activity of protein C, as suggested by the examiner during the interview. Applicants understand that these amendments overcome the first basis for rejection.

Applicants also have amended claim 12 to delete the Markush group, as suggested during the interview. Applicants understand that this amendment overcomes the rejection of claim 12.

Applicants also have deleted the Markush group from claim 14. Since amended claim 14 is directed to a "product" that is required by the process of claim 12, applicants believe that amended claim 14 fully complies with the enablement requirements of §112, first paragraph. That is, the specification provides a method of making transgenic mammals containing the long WAP promoter, and the specification teaches how to use transgenic mammals that secrete a polypeptide in milk.

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Finally, applicants have amended claim 16, as suggested by the examiner in a communication dated August 6, 1996 (Paper No. 27).

In light of the amendments and remarks above, applicants respectfully request the examiner to withdraw the rejection of the claims under the first paragraph of 35 USC §112. Reconsideration of the claims is respectfully requested

CONCLUSION

Applicants request reconsideration of the claims on their merits and respectfully solicit early notification of an allowance. If Examiner Crouch should have any questions or believes a telephone discussion would expedite prosecution, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Date

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